FEB 2 5 2005

K043010

Abbreviated 510(k) Notification: Device Summary

Submitter:

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Contact: Harlan Van Matre (see above)

Trade Name: H3+
Common Name: Holter Analysis Recorder
Classification Name: Medical Magnetic Tape Recorder (based on classification for original parent device.) (Per 21 CFR 870.2800)

Legally marketed devices to which S. E. is claimed

The H3+ Holter Recorder is an addition to the Mortara Holter Recorder family and is substantially equivalent to the following legally marketed predicate devices:

- Mortara H12+ Holter Recorder (K021373)
- Ela Medical Spiderview (K032466)
- Braemer / Phillips Digitrack Plus (K993617)

Description:

The H3+ Holter Recorder is intended for use as part of a Holter Analysis system and is designed to be used in conjunction with the Mortara H-Scribe Holter Analysis system. The H3+ Holter Recorder provides two or three channels of continuous ECG data recorded over a 24-hour or 48-hour period.

The H3+ is a Holter Recorder offering micro-sized, extremely lightweight patient utility. Using existing Mortara approved technology, the H3+ acquires, digitizes and stores data to be analyzed by the H-Scribe Holter System. The H-Scribe analyzes prerecorded patient's ECG data that has been stored by the H3+ recorder. The cardiac data provided by H-Scribe is used by trained medical personnel to assist in the diagnosis of patients with various rhythm patterns.

The H3+ provides the ability to choose between a 3-Channel patient cable to record modified leads II, III and V; and a 2-Channel patient cable to record bipolar leads positioned according to clinician preference. The 3-Channel 5-lead patient cable allows for recording modified leads II, III and V. The 2-Channel 5-lead patient cable allows for recording two bipolar leads. Either patient cable can be used with the H3+ according to user preference. A LCD screen and Enter button allow for checking the lead quality during patient hook-up and starting the recording.

The H3+ uses a single AAA alkaline battery and stores acquired ECG data in internal, non-volatile memory. Stored ECG data will be downloaded for analysis to the H-Scribe, a PC based Holter Analysis system, via a standard USB interface. The recorded data will remain in memory until it has been cleared by the clinician.

K043010

Intended use:

The H3+ Holter recorder is intended to acquire, record and store up to 48 hours of ECG data of patients that have been connected to the Mortara H3+ recorder and are undergoing Holter monitoring. The H3+ performs no cardiac analysis by itself and is intended to be used with the Mortara H-Scribe Holter analysis system (K004017) or other compatible Holter Analyzer. ECG data prerecorded by the H3+ is acquired and analyzed by the H-Scribe. In turn the cardiac data and analysis provided by H-Scribe Holter system will be reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.

Indications for use:

The H3+ is indicated for use in a clinical setting, by qualified medical professionals only, for recording ECG data of patients requiring ambulatory (Holter) monitoring of 24 hours. The Mortara Holter Recorder H3+ is not a life-supporting device. It is diagnostic tool intended to acquire, record and store ECG data of patients requiring ambulatory (Holter) monitoring of 24 or 48 hours. Such monitoring is most frequently used for the purpose of prospective and retrospective cardiac data and arrhythmia analysis.

Holter analysis is appropriate for the indications below:

- Evaluation of adult patients with symptoms suggesting arrhythmia
- Evaluation of adult patients with pacemakers
- Reporting of time domain heart rate variability
- Evaluation of a patients response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery.)
- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients
- Clinical and epidemiological research studies
- Infant patient evaluation is limited to QRS detection only

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mortara Instrument Inc.
c/o Mr. Harlan L. Van Matre
Manager, Quality Assurance and Regulatory Affairs
7865 North 86th Street
Milwaukee, WI 53224-3431

Re: K043010
Trade Name: Mortara Holter Recorder H3+
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: II (two)
Product Code: MWJ
Dated: January 21, 2005
Received: January 25, 2005

Dear Mr. Van Matre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K043010

Device Name: **Mortara Holter Recorder H3+**

The H3+ Holter recorder is intended to acquire, record and store ECG data of patients that have been connected to the Mortara H3+ recorder and are undergoing Holter monitoring. The H3+ acquires, digitizes and stores data to be analyzed by the H-Scribe Holter analysis system. The H3+ performs no cardiac analysis by itself and is intended to be used with the H-Scribe Holter analysis system (K004017). ECG data prerecorded by the H3+ is acquired and analyzed by the H-Scribe. In turn, the cardiac data and analysis provided by H-Scribe Holter analysis system will be reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.

The H3+ is indicated for use in a clinical setting, by qualified medical professionals only, for recording ECG data of patients requiring ambulatory (Holter) monitoring of up to 48 hours. Such monitoring is most frequently used for the purpose of prospective and retrospective cardiac data and arrhythmia analysis. Holter analysis is appropriate for the indications below:

- Evaluation of adult patients with symptoms suggesting arrhythmia
- Evaluation of adult patients with pacemakers
- Reporting of time domain heart rate variability
- Evaluation of a patients response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery.)
- Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients
- Clinical and epidemiological research studies
- Infant patient evaluation is limited to QRS detection only

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter Use**_____
(Per 21CFR801.109)

(Optional Format 1-2-96)

B Symmons

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043010